

REMARKS

Claims 1-54 were pending prior to entry of the present amendment. In this Reply, claims 1, 6, 33, 47 and 54 have been amended, as discussed in more detail below; claim 2-5, 7-32, and 34-46 have been deleted; and new claims 56-62 have been added herein. As such, claims 1, 6, 33, 47, 54, and 56-62 pending and reconsideration of the application is respectfully requested.

Basis for the claim amendments may be found throughout the specification and claims as filed. For example, and without limitation, claim 1 is based on a combination of original claims 1, 4, 5, 24 and 27. The "variable mechanical ratio" of claim 27 is expressed structurally, and comes from Figures 19-19d and the associated description at page 52, line 13 to page 53, line 3 (see PCT Publication No. WO2005/04435). New sub-claims 56-61 are also supported by the disclosure of Figures 19c and 19d. New sub-claim 62 is drawn from claim 47.

Applicants address each of the objections and rejections in the order in which they appear in the Action.

I. Objection to Drawings Addressed

The Action objects to the drawings for failing to comply with 37 CFR §1.83(a) and 37 CFR §1.84(p)(4). Applicants respectfully traverse this objection. The drawings show all features in the claims now pending. The Examiner's attention is drawn to Figures 19c and 19d, which clearly show the dual-gradient profile 425a, 425b and smooth break point 445 (see description of these figures in PCT Publication No. WO2005/044354, page 52, lines 13-25).

With regard to the other objection, the description of Figures 1 to 3 have been amended to remove reference numbers 20, 21 from the feature "finger-operable member" and reference number 28 from the feature "pre-load means."

II. Information Disclosure Statements

Applicants note that Reference Nos. 27 and 30 listed on the Form PTO-1449 submitted on May 3, 2006 were not considered. Applicants apologize for the inconvenience caused by the failure to provide copies of the references. The foreign patent references are attached herewith, along with the appropriate statement and fee and a new Form PTO-1449. Applicants request that the Examiner consider the references and return a fully-initialed copy of the Form PTO-1449 with the next communication.

III. Section 112 Rejection Overcome

Claims 1-54 have been rejected under 35 USC §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection, as the claims have been amended to remove the "means" language. All claims now specify the lever in terms of "at least one lever". Further, in claim 47, the second, narrower range has now been removed and made the subject of new sub-claim 62.

In light of these amendments, it is asserted that claims are "definite" within the meaning of section 112, and the rejection should be withdrawn.

IV. Section 102(e) Rejection Overcome

Claims 1-54 have been rejected under 35 USC §102(e) as being anticipated by US Publication No. 2005/0224525 (Davies *et al.*). Applicants respectfully traverse this rejection.

Claim 1 and all claims depending directly or indirectly therefrom, are not anticipated by Davies (US2005/0224525¹) since claim 1 requires that the container contain a fluid medicament formulation having a viscosity of from 10 to 2000 mPa.s at 25°C. The Examiner has overlooked the fact that this is a positive feature of claim 1. It is therefore immaterial for novelty whether Davies discloses a dispenser which is able to be used with such a formulation, as asserted by the Examiner. What is important for

¹ Our ref.: PG4925US

novelty is that there is no clear and unambiguous disclosure in Davies of the dispenser therein containing a formulation conforming to the requirements of claim 1.

Claim 1 is further distinguished from Davies by the requirement for the pre-load to be formed by one of the surfaces of the at least one lever and actuating member having a dual-gradient profile comprising first and second surface portions which are respectively a concave, high gradient surface portion and a convex, low gradient surface portion.

Claim 1 is the sole independent claim. As Claim 1 is novel and non-obvious over the prior art of record, so too, at least by dependency, are the remaining claims. For this reason, the following submissions with respect to the prior art are limited to claim 1 and then applied to the other claims. Applicants, however, reserve the right to argue for the independent patentability of the other claims, if the need arises.

V. Section 103(a) Rejections Overcome

A. Claims 1-10, 12, 15, 18, 21, 24, 27-28, 30-33, 36-48, and 54 have been rejected under 35 USC §102(a) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over PCT Publication No. WO 03/029105 (Simon *et al.*) in view of US Patent No. 6,745,760 (Grychowski *et al.*); claims 16-17, 29, and 34-35 have been rejected under 35 USC §103(a) as being unpatentable over Simon *et al.*, as applied to claim 1, and further in view of Grychowski *et al.*; claims 11, 13-14, 19-20, 22-23, and 25-26 have been rejected under 35 USC §103(a) as being unpatentable over Simon *et al.* and Grychowski *et al.* as applied to claims 21, 24, 8, 12, or 18, and further in view of US Patent No. 4,807,786 (Gueret); claim 49 has been rejected under 35 USC §103(a) as being unpatentable over Simon *et al.* Grychowski *et al.* as applied to claim 47, and further in view of US Patent No. 5,190,029 (Byron *et al.*); lastly, claims 50-53 have been rejected under 35 USC §103(a) as being unpatentable over Simon *et al.* and Grychowski *et al.* as applied to claim 47, and further in view of US Patent No. 6,568,389 (Rand *et al.*). Applicants respectfully traverse each of these rejections, as they potential pertain to the now pending claims.

As the Examiner will note, Simon (WO03/029105) does not disclose a dispenser of the same structure required by claim 1; e.g. at least one lever which pivots inwardly to apply a force to an actuating member at the neck of the container. Moreover, in Simon the levers are not pivotably supported at a lower end thereof, as claimed.

Grychowski (US6745760), like Simon, this does not disclose a dispenser having at least one lever which is pivotally supported at its lower end.

There is also no disclosure in Simon or Grychowski of a pre-load comprising a surface having a concave, high gradient portion and a convex, low gradient portion.

Accordingly, the asserted combination of Simon and Grychowski would not result in a dispenser as claimed. For this reason, the claims are not rendered obvious by such a combination.

Moreover, none of the other references cited against the sub-claims would make up for the short-fall in the disclosures of Simon and Grychowski.

For these reasons, the claims are not rendered obvious by the teachings of Simon, Grychowski, Gueret, Byron *et al.*, nor Rand *et al.* alone or in combination.

VI. Double Patenting Rejection Overcome

Claims 1-27 and 34-46 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of US Publication No. 2005/0224525 (Davies). Applicants respectfully traverse this rejection.

Claim 1 is distinguished from Davies by the requirement for the pre-load to be formed by one of the surfaces of the at least one lever and actuating member having a dual-gradient profile comprising first and second surface portions which are respectively a concave, high gradient surface portion and a convex, low gradient surface portion.

Applicants respectfully assert that the obviousness-type double patenting objection should be withdrawn, since claim 1 is not an obvious derivative of any claim in Davies due to this distinguishing feature.

Davies' claims does not disclose or suggest such a feature, and therefore does not render the instantly claimed subject matter obvious.

VII. Conclusion

All claim rejections being addressed in full, Applicants respectfully request the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance. Should the Examiner have any questions regarding the foregoing, Applicants respectfully request that the Examiner contact the undersigned, who can be reached at (919) 483-8022.

Respectfully submitted,

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